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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/743,080

12/23/2003

Atsushi Tomokuni

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT

PAPER NUMBER

1611

NOTIFICATION DATE

DELIVERY MODE

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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/743,080	Applicant(s) TOMOKUNI, ATSUSHI	
	Examiner Lakshmi S. Channavajjala	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7, 9, 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of response and declarations dated 12-9-09 is acknowledged.

Claims 1-7, 9 and 11-19 are pending in the instant application.

The following rejection of record has been maintained:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9 and 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,346,507 to Watanabe et al (Watanabe) in view of EP 103910 (EP submitted on PTO-1449 on 7-16-08) and US 6,333,362 to Lorant OR over Watanabe et al in view of US 6,333,362 to Lorant.

Instant claim 1 is directed to a skin cleansing composition comprising:

- (A) 3 to 80 wt. % of an oil component,
- (B) 1 to 45 wt. % of a hydrophilic nonionic surfactant,
- (C) 1 to 45 wt. % of a lipophilic amphiphile which is at least one amphiphile selected from the group consisting of fatty alcohols having 8 to 25 carbon atoms, fatty acids having 8 to 25 carbon atoms and monoalkylphosphoric acids having 8 to 25 carbon atoms,
- (D) 3 to 80 wt. % of a water soluble solvent and
- (E) 3 to 80 wt. % of water,

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and having an isotropic liquid phase exhibiting a bicontinuous structure wherein, the weight ratio of the water soluble solvent (D) to the sum of the hydrophilic nonionic surfactant (B) and lipophilic amphiphile (C), $(D)/((B)+(C))$, is 1 or greater.

Watanabe teaches a liquid crystal composition in the form of a bi-continuous type microemulsion (col. 6, L 63-67) in makeup removing (cleansing) compositions for skin and hair. Watanabe teach liquid crystal microemulsions comprising 10-60% of a nonionic surfactant, 1-50% of a water-soluble substance with a hydroxyl group, 1-70% of silicone oil, up to 10-60% water (col. 2), which meet the instant components B, D, A and E respectively of claim 1. The specific surfactants, oils, solvents with OH groups are all described in col. 3, L 10 through col. 4, L 5 of Watanabe.

The specific nonionic surfactants of Watanabe in col. 3, L 11-28, include those recited in instant claims 5 and 6 (ex: polyethylene glycol fatty acid ester). The water soluble solvents of Watanabe (col. 3, L 29-54) read on those of instant claim 9. For the claimed oils, Watanabe teaches hydrocarbon oils such as isoparaffin of claims 3 and 4 and hence the viscosity of claim 2 is implicit. Watanabe also teaches other oils (col. 4, L 35-50).

The amounts or percentages of components A, B, D and E in claims 1, 11, 13, 15 and 16 overlap with those taught by Watanabe.

While Watanabe does not teach the exact HLB of the hydrophilic surfactants of claim 1, 5 and 12, Watanabe teaches the surfactants for forming a surfactant phase, as also required in the instant application. Besides the surfactants described as nonionic by Watanabe includes the same surfactants described and claimed. Accordingly, burden is

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shifted to applicants to show that the surfactants do not meet the claimed HLB values.

Instant claim 17 does not recite any specific substrate, whereas Watanabe recognizes cleansing or makeup removing compositions impregnated on tissue paper (background section of Watanabe).

The composition of Watanabe has a one phase system, either a liquid crystal phase and/or an isotropic surfactant continuous phase (col. 2, L 57-65). Watanabe states that that the mixture of nonionic surfactant, water soluble substance having a hydroxyl group, silicone oil in water form a homogenous reversed micelle isotropic solution, which is considered to be a bi-continuous type microemulsion. Watanabe further identifies nonionic surfactants to be amphipathic in nature for emulsifying the ingredients homogeneously. However, Watanabe fails to teach instant component C i.e., a lipophilic amphiphile that is at least one amphiphile selected from the group consisting of fatty alcohols having 8 to 25 carbon atoms, fatty acids having 8 to 25 carbon atoms and monoalkylphosphoric acids having 8 to 25 carbon atoms.

EP teaches topical skin care composition in the form of a stable isotropic emulsion comprising 9% to 89% petrolatum, 10% to 90% water, 5% to 25% glycerin, up to 10% emulsifiers etc (abstract) for delivering active agents and emollients (pages 7-8). EP teaches emollients and skin conditioning agents such as fatty acids, fatty alcohols (page 8, Last paragraph and further Example A and B on page 26) and reads on the instant amphiphilic surfactants of the instant claims.

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Lorant teaches a device comprising microemulsion for cleansing and care of the skin. The composition of Lorant comprises oil, at least one nonionic emulsifier, at least one foaming surfactant and water (col. 3, L 1-10 & L 42-49). For the oils, Lorant teaches the claimed silicone oils as well as fatty acids and fatty alcohols (col. 5, L 10-45). The nonionic emulsifiers of Lorant (col. 5, L 46-col. 6, L 25) read on the instant claimed one. The foaming surfactants according to Lorant may include any on the anionic, nonionic, cationic or amphoteric surfactants (col. 6, L 26-67). Lorant additionally teaches inclusion of coemulsifiers in the composition in an amount of 0.5 to 30% and includes the instant fatty alcohols of C12-C22, which is within the claimed 8 to 25 carbon atoms.

Thus, While EP does not teach fatty alcohol such as cetyl alcohol as coemulsifiers, the teachings of Lorant provide evidence that the fatty alcohol also acts as a coemulsifiers. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to the emollients such as the fatty alcohols or fatty acids of EP OR include fatty alcohols of Lorant, in the compositions of Watanabe because EP suggests the claimed fatty acids and fatty alcohols as emollients and conditioner for treating dry skin and providing a barrier protection and Lorant suggests the use of C12-22 fatty alcohols as coemulsifiers as well as oils. Further, Lorant also suggests fatty alcohols such as oleyl alcohols, stearyl alcohol etc., as an essential oil component in preparing a microemulsion. Further EP states that the delivery of emollients and conditioners is optimum with the isotropic emulsion containing the components such as petrolatum, water, glycerin, emulsifiers. Therefore, one of an ordinary skill in the art would have expected not only cleansing and conditioning of the

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skin with the fatty acids or fatty alcohols of EP in the cleansing compositions of Watanabe but also for preparing microemulsions of suitable micron sizes because Lorant suggests fatty alcohols as both oily components and also coemulsifiers.

With respect to claimed ratio of the component D to the sum of components B and C being 1 or greater, all of the references are drawn to preparing emulsions in cleansing compositions and therefore optimizing the individual amounts of an emulsion without compromising the separation of phases would have been within the scope of a skilled artisan.

Response to Arguments

Applicant's arguments and two declarations of Atsushi Tomokuni under 37 CFR 1.132, filed 12-9-09, have been fully considered but they are not persuasive.

Applicants argue that instant skin cleansing composition is not disclosed or suggested by the cited prior art and that the references fail to identify a lipophilic amphiphile as a component of an isotropic liquid phase exhibiting a bicontinuous structure. Applicants argue that even though Watanabe teaches an isotropic surfactant bicontinuous phase, Watanabe lacks the claimed lipophilic amphiphile (of claim 1). It is argued that the basic deficiencies of Watanabe have not been cured by Lorant or EP because EP teaches fatty acids and fatty alcohols as dry skin and barrier protection and Lorant teaches the compounds as coemulsifiers.

In response to applicant's argument that EP teaches fatty acids and fatty alcohols as dry skin and barrier protection and Lorant teaches the compounds as coemulsifiers and none of the references teach claimed amphiphiles for bicontinuous structures, it is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., *In re Kahn*, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006). One of ordinary skill in the art need not see the identical problem addressed in a prior art reference to be motivated to apply its teachings.”); *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972) (discussed below); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991). Additionally, it is evident from the teachings of Watanabe that isotropic bicontinuous emulsions can be formed without the claimed component c), because Watanabe teaches bicontinuous emulsions even without the claimed component c). Thus, the motivation to add the compounds of Lorant and EP that read on instant c) may be different (dry skin treatment, barrier protection or coemulsifiers) and not necessarily for forming bicontinuous emulsion.

Applicant argue that they have previously submitted evidence that addition of a lipophilic amphiphile to a liquid crystal-phase coexisting system according to Watanabe et al. does not provide for the claimed composition. It is argued that the Tomokuni declaration tested whether there was formation of an isotropic liquid phase exhibiting a bicontinuous structure having a lipophilic amphiphile incorporated therein by adding a lipophilic amphiphile to the liquid crystal composition of Watanabe et al. Applicant state that the first Tomokuni declaration employs Example 1 of Watanabe et al. U.S.

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6,346,507 was produced as Composition A, Compositions B-F was prepared by adding 1-dodecanol, a lipophilic amphiphile. Corresponding amounts of water were reduced in order to maintain proportions of the remaining components. It is argued that Composition F, while visibly transparent, was in the form of a w/o type microemulsion and failed to demonstrate light polarization and also failed to dissolve a water-soluble dye. It is argued that none of Compositions A-E provided any evidence of an isotropic solution having a bicontinuous structure in terms of transparency or light polarization and were illustrative of a liquid crystal-phase coexisting system. Thus, applicants argue that they provide evidence that an isotropic liquid phase exhibiting a bicontinuous structure does not naturally flow from the suggestion of the cited references. Therefore, it is argued that the claimed invention having an isotropic liquid phase exhibiting a bicontinuous structure would not have been obvious and accordingly, withdrawal of the rejection under 35 U.S.C. 103(a) is respectfully requested.

Examiner notes that the declarations of 12-9-09 (5 page) and 5-12-09 provide the same results. While the declarations have been considered, the results provided are not persuasive because applicants have not compared any of the compositions of bicontinuous phase of Watanabe altered with the amphiphile of (EP or Lorant) with that of instant compositions. Watanabe not only teaches liquid crystal phase but also teaches that preparing a bicontinuous surfactant phase where multiple phases coexist. Further, it is unclear as to how the same components of the instant result in bicontinuous structure and not the compositions tested (though they all have the same components of instant claims). Further, even though applicants argue that the

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compositions tested in the declaration do not produce the claimed bicontinuous phase, the photographs provided are not clearly legible and do not show any distinction between the various samples tested. It was previously conveyed (Interview summary of 11-10-09) by the examiner to provide original color photographs that show clear distinction. Additionally, the examiner's arguments (of 8-10-09) pertaining the declaration of 5-12-09 are incorporated herein.

With respect to the second declaration of Tomokuni (4 pages), once again applicants employed the liquid crystal composition of Watanabe as a comparison composition and not a bicontinuous surfactant phase (Watanabe) where multiple phases coexist. It is unclear how one can compare different types of compositions (liquid crystal and bicontinuous) in order to show that cleansing ability. Further, while the cleansing test shows that example 1 has greater cleansing power than untreated or reference 1 (Watanabe composition), as explained above, the comparison was made between a liquid crystal (of Watanabe) versus instant bicontinuous phase and not between the bicontinuous phase of the instant and the bicontinuous phase of Watanabe modified with Lorant or EP. Furthermore, while instant claims broadly recite the components A-E, the composition of example 1 is specific to the components of table on page 2 of the declaration and thus is not of same scope as that of the instant claimed composition. With respect to the dye solubility tests of the second declaration, once again the photographs presented are not clear for one to be able to analyze the results. Additionally, the dye solubility tests do not include the prior art compositions in comparison with the example (1, 9 and 10) compositions and hence one cannot

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reasonably conclude from the results presented that only instant compositions and not the prior art compositions would solubilize both water and oil soluble dyes.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 23, 2010